

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

PRECISION MEDICAL, INC.,	:	
Plaintiff,	:	CIVIL ACTION
	:	
v.	:	
	:	
GENSTAR TECHNOLOGIES CO.	:	
and	:	
TENACORE HOLDINGS, INC,	:	No. 10-5161
Defendants.	:	

MEMORANDUM

Schiller, J.

May 3, 2011

The parties are competitors in the intermittent vacuum regulator market. Precision Medical claims that Defendants Genstar Technologies (“Genstar”) and Tenacore Holdings (“Tenacore”) are infringing on its patent. Precision Medical moved for a preliminary injunction to halt this purported infringement, and the Court conducted a hearing on the motion. The Court concludes that Precision Medical has failed to demonstrate a likelihood of success on the merits or that it will suffer irreparable harm without a preliminary injunction. Therefore, the motion is denied.

I. BACKGROUND

A. Precision Medical and the ’308 Patent

Michael Krupa co-founded Precision Medical in 1984 and has been its president since that time. (Krupa Decl. ¶ 4; Mar. 14, 2011 Prelim. Inj. Hr’g Tr. [Hr’g Tr. I] at 84.) Clyde Shuman is the CEO of Precision Medical. (Hr’g Tr. I at 160.) The company designs, develops and manufactures health care products. (Shuman Decl. ¶ 3.) The company first made oxygen and air flow meters, and by 1988, had made about \$2 million in sales. (Hr’g Tr. I at 162.) Between 1997 and 1998, Precision Medical began making vacuum regulators. Although sales in that market were initially small, the

company has seen its sales of vacuum regulators greatly increase. (*Id.* at 162, 166.) Vacuum regulators help patients breathe by preventing internal fluid buildup. (*Id.* at 89.) They are used in hospitals, nursing homes and other facilities that provide critical care. (Krupa Decl. ¶ 7.)

Precision Medical owns United States Patent 5,599,308 (“the ’308 Patent”), entitled “Intermittent Vacuum Regulator with Timing Module.” (Shuman Decl. ¶ 2.) The abstract states that the ’308 Patent is for “[a] vacuum regulator having a timing module that provides intermittent vacuum and is modular in design permitting easy removal and replacement without having to disassemble the entire vacuum regulator.” (Richard Gilly Decl. Ex. A [’308 Patent].) Krupa is the inventor of the vacuum regulator that is the subject of the ’308 patent. (Hr’g Tr. I at 88; Krupa Decl. ¶ 6.) Krupa worked for approximately two and a half years to develop the product. (Hr’g Tr. I at 96.) The patent was filed on September 19, 1995 and was awarded on February 4, 1997. (’308 Patent.)

An intermittent vacuum regulator is normally connected to a source of vacuum, such as a wall outlet in a hospital. (Krupa Decl. ¶ 8.) The term “intermittent” refers to the alternating nature of the vacuum between periods of time in which vacuum is supplied and periods of time in which the vacuum is shut off and the patient is exposed to ambient air. (Pl.’s Mem. of Law in Supp. of Mot. for a Prelim. Inj. [Pl.’s Mem.] at 2-3; Krupa Decl. ¶ 9.) Plaintiff’s device can be adjusted to operate in its intermittent mode and to vary the amount of vacuum supplied. (Krupa Decl. ¶ 15.) According to Krupa, “[b]y alternating between providing ambient pressure and then vacuum, the ’308 Patented invention aids in the release of blockages ensuring more effective and less traumatic aspiration than other prior art vacuum regulators.” (Pl.’s Mem. at 3 (citing Krupa Decl. ¶ 11).) The intermittent timing process is necessary to ensure that continuous suction does not damage bodily

tissues. (Hr'g Tr. I at 89-90.)

Prior to filing the patent, Precision Medical invested \$400,000 in research and development of the vacuum regulator disclosed by the '308 Patent. (Shuman Decl. ¶ 5.) Since it filed the patent, Precision Medical has spent another \$350,000 in capital improvements for tooling and equipment for ongoing research and development. (*Id.*) Precision Medical claims to be the recognized leader for continuous/intermittent vacuum regulators. (*Id.* ¶ 8.) It sells more than \$5.56 million per year of vacuum regulators and has sold over \$57.37 million in vacuum regulators since 2002. (*Id.*) Sales of vacuum regulators comprised 15% of Precision Medical's revenue in 2010. (*Id.*) Precision Medical controls approximately 25% of the total market for both continuous/intermittent and continuous regulators. (*Id.* ¶ 9; Hr'g Tr. I at 202-03.)

B. Tenacore and Genstar

Brand Caso co-founded Tenacore in 2000 along with CEO Peter Bonin; the two men are its only shareholders. (Caso Decl. ¶ 4.) Tenacore is a California corporation that sells medical equipment, including VeeVo Suction Regulators, which are alleged to be infringing products in this case. (*Id.* ¶ 5.) Since Tenacore began marketing and offering its VeeVo Suction Regulators for sale in December of 2009, it has sold about 1,000 of them; its market share is less than 1% of the total United States market. (*Id.* ¶¶ 8-9.) These 1,000 units were sold for an average of approximately \$200 per unit. (*Id.* ¶ 10.)

Genstar also sells an intermittent vacuum regulator that Precision Medical claims infringes the '308 Patent. It began selling the accused regulators around December of 2007. (Tina Kuo Decl. ¶ 3.) From May of 2008 to December of 2008, Genstar sold an average of over 200 units per month. (*Id.* ¶ 4.) In 2008, Genstar sold approximately 1,978 units; in 2009, it sold approximately 6,545

units; and in 2010, it sold approximately 6,718 units. (*Id.* ¶ 5.) Sales of intermittent vacuum regulators have become an increasingly large proportion of Genstar's overall sales and Genstar estimates it has grossed about \$2.3 million in sales of the accused products. (*Id.* ¶¶ 6-7.)

II. STANDARD OF REVIEW

District courts may grant injunctions to prevent patent infringement. 35 U.S.C. § 283. Because Plaintiff seeks a preliminary injunction to end alleged infringement of its patent, this Court must apply the substantive standards laid out by the Federal Circuit. *See Lawman Armor Corp. v. Winner Int'l, Inc.*, Civ. A. No. 01-1605, 2002 U.S. Dist. LEXIS 1431, at *24 n.2 (E.D. Pa. Jan. 23, 2002) (citing *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1451 n.12 (Fed. Cir. 1998)). A patent holder is entitled to a preliminary injunction if it can demonstrate: (1) a reasonable likelihood of success on the merits; (2) irreparable harm if the injunction is not granted; (3) that the balance of hardships tips in its favor; and (4) the injunction's favorable impact on the public interest. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1050 (Fed. Cir. 2010); *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1298 (Fed. Cir. 2009). Although no single factor is dispositive, the movant must establish a likelihood of success on the merits and irreparable harm or the injunction will not issue. *Altana Pharma. AG v. Teva Pharms. USA, Inc.*, 566 F.3d 999, 1005 (Fed. Cir. 2009); *Quad/Tech, Inc. v. Q.I. Press Controls B.V.*, 701 F. Supp. 2d 644, 649 (E.D. Pa. 2010).

III. DISCUSSION

A. Likelihood of Success on the Merits

To demonstrate a likelihood of success on the merits, the patentee must show that it will

likely prove infringement of one or more of the claims of the patent at issue and that at least one of those infringed claims will likely survive a validity challenge posed by the alleged infringer. *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001). “[T]he court views the matter in light of the burdens and presumptions that will inhere at trial.” *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1376 (Fed. Cir. 2009).

1. Infringement

An infringement analysis requires two steps: first, the scope of the claim must be determined; and second, the properly construed claim is compared with the accused device to determine whether all of the claim limitations are present either literally or by substantial equivalent. *Amazon.com*, 239 F.3d at 1351. Once a claim is properly understood, a determination can be made whether the claim “reads on” an accused device or method. *Id.*

Precision Medical asserts that Defendants’ products infringe Claims 1, 2, 3, 4, and 6 of the ’308 patent, both literally and under the doctrine of equivalents. “Literal infringement will only be found where each and every limitation of the patent claim at issue is literally met in the accused device.” *Lawman Armor*, 2002 U.S. Dist. LEXIS 1431, at *27-28 (citing *Novo Nordisk of N. Am., Inc. v. Genetech, Inc.*, 77 F.3d 1364, 1371 (Fed. Cir. 1996)). The doctrine of equivalents, on the other hand, exists because “[t]he language in the patent claims may not capture every nuance of the invention or describe with complete precision the range of its novelty.” *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731 (2002). Thus, a patent’s scope includes both the literal terms of the claims and all equivalents to the claims described. *Id.* at 732 (citing *Winans v. Denmead*, 56 U.S. 330, 347 (1854)). Although the doctrine of equivalents renders patents less certain and may deter competitors from entering the market, the law protects inventors from those

who make unimportant and insubstantial alterations that, while outside the scope of the literal claim, add nothing to the invention. *Festo Corp.*, 535 U.S. at 732-33.

A patentee shows equivalency under this doctrine if the accused product “performs substantially the same function, in substantially the same way, to achieve substantially the same result, as disclosed in the claim.” *Abbott Labs.*, 566 F.3d at 1296 (citing *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950)); *see also Baran v. Med. Device Techs., Inc.*, 666 F. Supp. 2d 776, 791 (N.D. Ohio 2009) (noting that doctrine of equivalents can be analyzed using “function-way-result test.”). “Equivalency may also be proven where the differences between the invention as claimed and the accused product or process are insubstantial.” *Abbott Labs.*, 566 F.3d at 1297 (citing *Hilton Davis Chem. Co. v. Warner-Jenkinson Co.*, 62 F.3d 1512, 1517-18 (Fed. Cir. 1995) (en banc)). The doctrine of equivalents must be applied on a claim-by-claim basis rather than on the invention as a whole. *Abbott Labs.*, 566 F.3d at 1296. (“[A] generalized showing of equivalency between the claim as a whole and the allegedly infringing product or process is not sufficient to show infringement.”) A patentee however, may not use the doctrine of equivalents to capture additional coverage for his invention. *See Lawman Armor*, 2002 U.S. Dist. LEXIS 1431, at *44 (“It is true that a patentee may not assert a range of equivalents that encompasses prior art.”); *see also In re Gabapentin Patent Litig.*, 393 F. Supp. 2d 278, 292 (D.N.J. 2005) (“There are two major limitations on the doctrine of equivalents. A patentee cannot recapture subject matter surrendered during prosecution to obtain patentability. Nor can a patentee claim that which could not have been patented based on prior art.”).

“[T]he claims of a patent define the invention to which the patentee is entitled the right to exclude.” *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed.

Cir. 2004). A court must construe the claims of the patent in accord with the plain meaning of its terms. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005). The words of a claim are given their ordinary and customary meaning. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). “[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.” *Phillips*, 415 F.3d at 1313. To construe the language of a claim, courts look at intrinsic evidence including the language of the claims themselves, the written description of the claims, and the patent’s prosecution history, which is the record created during the application process. *Lawman Armor*, 2002 U.S. Dist. LEXIS 1431, at *30 (citing *Vitronics*, 90 F.3d at 1582). Sometimes, the ordinary meaning of claim language is readily apparent, even to lay judges, and claim construction demands only applying the widely accepted meaning of the terms. *Phillips*, 415 F.3d at 1314. “In such circumstances, general purpose dictionaries may be helpful.” *Id.* Often, however, patentees use terms in a manner not readily ascertainable by lay judges; in such cases, the court turns to “those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean.” *Innova/Pure Water*, 381 F.3d at 1116. Included among these sources is “the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art.” *Id.*

The claims themselves offer substantial guidance as to the meaning of particular claim terms. *Phillips*, 415 F.3d at 1314. Context matters. *Id.* (“This court’s cases provide numerous similar examples in which the use of a term within the claim provides a firm basis for construing the term.”). Furthermore, term usage in one claim can often illuminate the meaning of the same term in other

claims. *Id.* Because the claims are part of a larger fully integrated document, they “must be read in view of the specification, of which they are a part.” *Id.* at 1315 (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995)). Indeed, the specification is the best guide to the meaning of a disputed term. *Phillips*, 415 F.3d at 1315-16 (quoting *Vitronics*, 90 F.3d at 1582). Thus, should the specification define a claim term in a manner different from the term’s ordinary meaning, “the inventor’s lexicography governs.” *Phillips*, 415 F.3d at 1316.

2. *Claim 1 of the '308 Patent*

Claim 1 reads:

1. An intermittent vacuum regulator having a timing module in combination with a valve means for controlling the position of said valve means between one of two states, said module comprising: a base plate having a plurality of channels and apertures for conveying vacuum pressure in a first state or ambient pressure in a second state;¹ a diaphragm assembly coupled thereto; a gear coupled to a lever arm that is in contact with said valve means; said diaphragm assembly having a diaphragm, coupled to said gear, that is exposed to a vacuum source and ambient pressure alternately said diaphragm disposed within said diaphragm assembly to form a movable wall of said diaphragm assembly, said alternating exposure causing said gear to move in a first direction or a second direction, respectively, movement in said first direction defining an off time and movement in said second direction defining an on time and also defining a timing ratio.

(‘308 Patent.) Precision Medical believes that both Defendants’ products are structurally identical to each other, a claim that Defendants do not dispute. Because the Court concludes that the accused devices do not include a “gear coupled to a lever arm,” the Court will only address that portion of

¹ The ‘308 Patent uses the word “state” immediately following the word “ambient.” This is a typographical error that was the subject of a September, 2010 Request for Certificate of Correction.

Claim 1, and also need not address dependant Claims 2, 3, 4, or 6.

Precision Medical concedes that Defendants' products do not literally infringe on this claim. Instead, it contends that the infringing products include "the insubstantial change of using a pin coupled to a lever arm, rather than a gear coupled to a lever arm." (Pl.'s Mem. at 13; *see also* Pl.'s Reply Mem. of Law in Supp. of Mot. for Prelim. Inj. [Pl.'s Reply] at 8-11; Pl.'s Mem. Summarizing Hr'g Testimony [Pl.'s Post-Hr'g Mem.] at 5-7.)

As described by Plaintiff, the gear is integrated into the lever arm at one end to form a geared lever arm, which contacts a push rod. (Pl.'s Mem. at 14.) "The push rod which is connected to the rolling diaphragm moves downward and rotates [the] geared lever arm counterclockwise. Once the two pivot points of the toggle spring cross over the center line of each other, the valve means flips to the ON state." ('308 Patent.) During the "on" state, "[t]he push rod is therefore driven upward and rotates the geared lever arm clockwise. Once the two pivot points of the toggle spring cross over the center line of each other, the valve means flips to the OFF state." (*Id.*)

According to Plaintiff, the doctrine of equivalent's "function-way-result" test is satisfied because: both structures perform the function of moving in either of two directions, they perform in substantially the same way, namely by translating the back-and-forth movement of a push rod into rotation of a lever arm; and they achieve substantially the same result of moving a toggle spring to flip the valve back and forth.

During the preliminary injunction hearing, Krupa described his invention and explained why he believed Defendants' devices infringed on the '308 Patent. The prior art included an intermittent vacuum regulator manufactured by Allied Healthcare which featured two vacuum reduction regulators, one of which supplied a constant vacuum to the second and a cycling mechanism. (Hr'g

Tr. I at 94.) Krupa's invention eliminated that structure, replacing it with a product that was smaller, modular, and more reliable. (*Id.* at 94-96.) The Precision Medical device works by having a vacuum line come up and underneath a valve and come down to the diaphragm assembly. When the unit is turned on, the vacuum comes up, goes across the valve, proceeds down through the needle valve, begins to evacuate air from a chamber, and compresses a spring. The spring stores energy and controls the timing of the vacuum regulator. Meanwhile, a push rod comes down, engages with the gear, and the lever arm winds the toggle spring. The toggle spring aligns with the two pivot points and when they come over each other's pivot point, the valve is flipped and the vacuum regulator enters the "on" state. The stored energy in the spring pushes the assembly back up, pushing the rod, and pulling in vacuum through the needle valve. (*Id.* at 104.) The vacuum in the chamber enters the atmosphere, and while the atmospheric air is pulled into the chamber, the vacuum goes to the patient. Precision Medical's intermittent vacuum regulator operates in a two-to-one ratio, meaning that the vacuum is on for twice as long as it is off to the patient. (*Id.* at 105.)

Krupa's description of the operation of the accused products, which he disassembled to learn how they worked, is, unsurprisingly, similar to his description of the workings of his invention. According to Krupa, Defendants' products work as follows: when vacuum is applied, the air is forced out of a chamber, a spring is compressed, and the lever arm is pulled back. (Hr'g Tr. I at 110.) When the lever arm pulls back in contact with the pin via a lever arm, which winds the toggle spring to store energy, it flips the valve. (*Id.*) Once the valve is flipped, the stored energy pushes the diaphragm assembly against the lever arm to wind the spring in the opposite direction, to flip the valve to enter a different state. (*Id.*) Krupa described the accused products as containing a lever arm which is attached to a toggle spring, with the other end of the toggle spring attached to a valve. (*Id.*

at 115.) The lever arm is connected by a pin to the push rod, which is part of the diaphragm assembly. (*Id.* at 116.) The pin takes the motion of the diaphragm and winds the toggle spring to get the pivot point of the toggle spring on one end, and the other end to align to flip the valve. (*Id.* at 116-17.) Thus, the pin moves in two directions. (*Id.* at 117.)

According to Genstar, “[t]o obtain its patent, Precision specifically claimed a gear connected to a lever arm because prior art regulators already included the other core components. Precision now seeks to abandon the very element that made its invention patentable by impermissibly broadening the definition of ‘gear’ to include anything but a gear. Precision cannot have it both ways.” (Genstar’s Opp’n to Pl.’s Mot. for Prelim. Inj. [Genstar’s Opp’n] at 7-8.) As Genstar views the infringement analysis, if a “gear” is a relatively simple structure construed according to its ordinary meaning and the specification, Genstar does not infringe. (*Id.* at 8.)

Genstar offers the following four reasons why the pivot pin in its vacuum regulator is not the equivalent of a gear. First, a gear is a relatively simple structural device and thus, the doctrine of equivalents is limited. (*Id.* at 13-14.) If the patentee wanted broader protection, it could have sought claims with fewer structural encumbrances. (*Id.* at 14.) However, it cannot expand the scope of its claim through the doctrine of equivalents. (*Id.*)

Second, the pin in Genstar’s product does not function as a gear and it does not accomplish its function in the same way as a gear. (*Id.* at 15.) A gear requires something else to put it in motion and, when actuated, a gear moves something else. (*Id.*) In Precision Medical’s invention, the gear receives the movement of the diaphragm via the push rod, and it causes the lever arm to rotate in response to that movement. (*Id.* at 15-16.) By contrast, Genstar’s product includes a push rod that directly pushes and pulls the lever arm, while the pivot pin merely holds both of them together. (*Id.*

at 16.) Not only do the functions differ, but Precision Medical uses a “pinion gear” coupled to a push rod in a “worm gear fashion.” (*Id.* at 16-17.) Genstar’s product functions by having a push rod directly push and pull the lever arm without any need for causing rotational forces or using a gear. (*Id.* at 17.) The pin is only a pivot point. (*Id.*; Mar. 15, 2011 Hr’g Tr. [Hr’g Tr. II] at 28.) The pin serves to hold the push rods and the lever arm together so they can move freely. (Hr’g Tr. II at 28.)

Third, the specification distinguishes between a gear and a pivot point and never offers any indication that a gear and a pivot point are synonymous. (Genstar’s Opp’n at 17.) Precision Medical disclosed but did not claim a pivot point which Genstar employs. (*Id.* at 18.) Fourth, Precision Medical’s equivalency argument would capture prior art vacuum regulators that include a pivot between a diaphragm/push rod and a lever arm. (*Id.* at 18-19.) If a patentee would be unable to sustain a claim due to the prior art, he is not entitled to that claim under the doctrine of equivalents.

Tenacore also disputes that its product includes the equivalent of a gear coupled to a lever arm. (Tenacore’s Resp. in Opp’n to Pl.’s Mot. for Prelim. Inj. [Tenacore’s Opp’n] at 7.) Indeed, Tenacore claims that its product has neither a gear nor a lever arm. Instead, it uses an “idler link connected by a pin with an end of an actuation rod and whose main purpose is merely to avoid having the end of the actuation rod floating freely during reciprocation.” (*Id.* at 8.) The idler link is thus not a “lever” or a “lever arm” as contemplated by the ’308 Patent. (*Id.*) Tenacore’s idler link pivots about a stationary brace and its opposite end is connected via the pin with the actuation rod. An end of a spring is connected with the idler link at the same distance from the brace as the pin. The idler link is not a “lever” or a “lever arm” because the actuation rod and the spring are connected with the idler link at the same point.

Tenacore offers its own interpretation of the function-way-result test for a “gear coupled to

a lever arm.” The “gear coupled to a lever arm” amplifies translation of a diaphragm push rod to cause a valve to change states. It does this by providing that the gear have teeth at a first radius from an axis of rotation that interact with corresponding teeth on the diaphragm push rod, and with the lever arm having a length from the axis of rotation that is much greater than the radius of the teeth. The result is that the geared lever arm moves and causes the valve means to pivot between “on” and “off.” Tenacore argues that the ’308 Patent includes greater movement of the valve compared to its product, which has no need of such amplification of movement. (*Id.* at 10-11.)

According to Tenacore, the function-way-result of its idler link has nothing to do with such amplification of motion. Rather, the idler link constrains the movement of the end of the actuation rod where an end of the spring is connected. (Tenacore’s Post Hr’g Closing Argument Against Pl.’s Mot. for Prelim. Inj. [Tenacore’s Post Hr’g Br.] at 10.) It does this by pivotably mounting one end of the idler link to a stationary brace and by connecting the other end of the idler link with the end of the actuation rod. (*See id.*) This causes the end of the spring to cross an imaginary line and causes the valve to change states. (Tenacore’s Opp’n at 12.)

3. *Analysis*

Infringement under the doctrine of equivalents in this case is a close question, made somewhat more difficult by the failure of Precision Medical to define the term “gear.” Instead, it elected to argue that however it is defined, Defendant’s products are substantially similar to a “gear.” A gear is defined as a “mechanism that performs a specific function in a complete machine” or as “a toothed wheel.” *Merriam Webster’s Collegiate Dictionary* 483 (10th ed. 1995); *see also* Definition of Gear, *The Free Dictionary*, <http://www.thefreedictionary.com/gear> (last visited April 25, 2011). Claim 1 refers to a “gear coupled to a lever arm that is in contact with said valve means.”

This is consistent with how the term “gear” is referenced in the ’308 Patent. The term “gear” appears in the specification as a method of describing the lever arm; that is, the specification repeatedly refers to a “geared lever arm.” Furthermore, the specification includes the following example of a “geared lever arm”: “(e.g., a pinion gear having a portion of its circumference integral with a lever arm) coupled to a lever arm) that are coupled in a worm gear fashion.” A “pinion gear” presumably refers to a rack and pinion, which is a type of “linear actuator” made up of gears. Rack and Pinion, *Wikipedia*, http://en.wikipedia.org/wiki/Rack_and_pinion (last visited Apr. 25, 2011). A rack and pinion involves a linear toothed bar or rod (the rack) that is meshed with the circular pinion. The pinion’s rotation causes the rack to move to the side. Gear, *Wikipedia*, <http://en.wikipedia.org/wiki/Gear> (last visited Apr. 25, 2011). A “worm gear is usually meshed with an ordinary looking, disk-shaped gear.” *Id.* The record before the Court provides no reason to deviate from the regularly understood meaning of “gear.”

The Court concludes that Plaintiff has failed to show a substantial likelihood of success on the merits because Precision Medical has failed to demonstrate that the accused devices achieve their result in the same way as the patented device. Specifically, the use of a pin rather than a gear works more than an insubstantial change between the patented product and accused devices.

According to Precision Medical, “the Accused Products have merely substituted a ‘pin P’ for the ‘gear’ called for by claim element (iii) of the ’308 Patent.” (Pl.’s Mem. at 16; *see also* Pl.’s Reply at 8-10). To support its position, Plaintiff relies upon *Odetics, Inc. v. Storage Technology Corp.*, 185 F.3d 1259 (Fed. Cir. 1999). *Odetics* involved robotic tape storage systems used to store, organize, and retrieve videotapes or computer data tapes. The plaintiff’s patent was for a tape cassette handling system which included a “rotary means” whose structure had “a rod providing the

axis of rotations, and a gear capable of receiving a force sufficient to cause the structure to accomplish the claimed ‘rotary’ function.” 185 F.3d at 1265. The defendant’s product used a “bin array,” described as a box-like set of tape slots or holders that slid linearly along a short track. The bin array rotated by using pins affixed to its bottom. As the bin array moved along its track, the pins came into contact with angled structures that exerted force against the pins, causing the bin array to rotate about a rod that formed its axis.

The Federal Circuit reinstated a jury verdict based on *Odetics*’s theory that its structure to accomplish a “rotary means” was equivalent to that in the defendant’s device. Specifically, the rotation in the plaintiff’s device was accomplished by exerting force against the teeth of the gear, thereby turning the bin about the rod. The defendant’s device accomplished rotation by exerting force against the pins, also turning the bin about the rod. Thus, the court held that there was testimony sufficient for the jury to find that the “rotary means” structure was equivalent to the “bin array” structure. *Id.* at 1269-70.

The Court disagrees that *Odetics* presents “an astonishing parallel to the facts of the present case.” (Pl.’s Mem. at 16.) As Genstar notes in its opposition, the patent at issue in *Odetics* claimed a “rotary means” and the court concluded that a jury could find based on the evidence that structurally a gear and a pin were equivalent “rotary means.” *Odetics*, 185 F.3d at 1270. Additionally, the way both structures accomplished the claimed “rotary means” and the result achieved, actuating the system, were equivalent. *Id.*

Here, however, the ’308 Patent claims a “gear coupled to a lever arm.” It does not generally claim a means of moving a structure in one of two directions or a means of translating the back-and-forth movement of a push rod. While Krupa’s testimony demonstrates that the Precision Medical

device and the accused devices accomplish the same result, the evidence does not support a finding that a gear is structurally equivalent to a pin. Precision Medical's argument is an attempt to capture additional matter beyond that permitted by the claims in the '308 Patent. To analogize, an individual can get from point A to point B using a number of means; for example, one can walk, or take a train or a bus, or a plane to get to where he or she wants to go. The '308 Patent specifies a method of getting from point A to point B, but Precision Medical seeks to expand that specification to include all methods of arriving at that final destination. Ultimately, the plane, the train, and the bus will achieve the same result, but if the '308 Patent speaks of the bus, Precision Medical cannot later complain when Defendants use the train.

In its post-preliminary injunction hearing briefing, Precision Medical continues to argue that, like its products, the accused products "activate by having a push rod interact with the lever arm through a coupling mechanism." (Pl.'s Post-Hr'g Mem. at 5.) All three products function in the same manner, specifically, turning about a fixed point; in the same way, namely by coupling the push rod to the lever arm; and achieving the same result, that is, causing a toggle spring to wind up and flip a valve back and forth between two states. (*Id.* at 5-6.)

Of course, the '308 Patent does not speak of "a coupling mechanism" but of a "gear coupled to a lever arm." Krupa conceded that the '308 Patent discloses a push rod coupled to a gear but that the accused products use a pin coupled to a lever arm. (Hr'g Tr. I at 118.) Nonetheless, he believes that the pin is equivalent to the gear because "you're taking a motion of in and out or up and down through this diaphragm assembly and converting that motion to the lever arm which goes through an arc" (*Id.* at 119-20.) Thus, the accused products accomplished the same result as his device: taking the movement of the diaphragm through the push rod, and connecting it to a lever arm to wind

a toggle spring to flip the valve. (*Id.* at 129-30.) In both cases, the lever arm rotates about a fixed point and creates an arc which winds the spring to store energy to flip the valve. (*Id.* at 151.)

Genstar concedes that its product accomplishes the same result as the Precision Medical product. (Genstar's Post-Hr'g Br. in Opp'n to Pl.'s Mot. for Prelim. Inj. [Genstar's Post-Hr'g Br.] at 12.) In Precision Medical's product, the gear contacts the push rod and pushes it down, causing the geared lever arm to move and wind the toggle spring. The accused products, however, do not include a gear coupled to a lever arm. Instead, the push rod directly pushes and pulls the free end of the lever arm and the pin couples the lever arm to the push rod. Thus, the pin plays no role in the movement of the push rod. It is simply a method of connection.

Finally, Precision Medical suggests that Krupa's testimony that he considered connecting the lever arm to the push rod with a pin but instead selected a gear demonstrates that a pin and a gear are equivalent. (Pl.'s Post-Hr'g Mem. at 6-7 (citing Hr'g Tr. I at 137).) Precision Medical relies on two cases to support its assertion that testimony of known interchangeability is direct evidence of equivalence: *Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1370-71 (Fed. Cir. 2010) and *Al-Site Corp. v. VSI International, Inc.*, 174 F.3d 1308, 1316 (Fed. Cir. 1999). These cases are distinguishable. Both involved a jury finding of equivalence under 35 U.S.C. § 112, ¶ 6, not a finding of equivalence in the context of a preliminary injunction motion. Furthermore, the Court finds that Krupa's statement that using a pin instead of a gear "wasn't any different [because] [i]t was a contact point that took a linear motion and converted it to a rotational motion" establishes that the patented device and accused devices achieve the same result, not necessarily that they do so in the same way. (Hr'g Tr. I at 137.) Ultimately, Plaintiff may be able to further develop this theory and convince a jury that the gear in Precision Medical's device and the pin in the accused devices

are equivalent. When seeking a preliminary injunction, however, a single statement that the inventor considered multiple ways to achieve his goal will not demonstrate infringement. This is particularly true here, as the Claim of the '308 Patent specifically references a gear.

The Precision Medical device employs a gear because that is what Claim 1 of the '308 Patent discloses. The Court will not grant a preliminary injunction based on a finding that a pin is equivalent to a gear because such a finding would permit Precision Medical to capture more than the claims of the '308 Patent allow. Because the Court concludes that Plaintiff failed to show a likelihood of success on the merits of its infringement claim, the Court need not address the validity of the '308 Patent at this time.

B. Irreparable Harm

1. Presumption of Irreparable Harm

Plaintiff contends that, “[i]n patent cases, irreparable harm is presumed where the patentee has clearly shown that it is likely to prevail on the merits.” (Pl.’s Mem. at 19-20.) Historically, this was a correct statement of law. *See Lawman Armor*, 2002 U.S. Dist. LEXIS 1431, at *48-49; *see also Amazon.com*, 239 F.3d at 1350. The Supreme Court, however, has recently addressed the four-factor test for granting an injunction. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006). In that case, MercExchange contended that eBay infringed its business method patent for an electronic market designed to facilitate the sale of goods between private individuals by establishing a central authority to promote trust among participants. *Id.* at 390. MercExchange won a jury verdict, but the district court denied its motion for a permanent injunction. The Federal Circuit reversed, applying its general rule that a permanent injunction against a patent infringer should issue “absent exceptional circumstances.” *Id.* at 391. The Supreme Court vacated the

Federal Circuit’s judgment and held that the language of the Patent Act did not warrant a departure from the traditional four-factor test. *Id.* at 392 (citing 35 U.S.C. § 283). The Court rejected the invitation to replace traditional equitable considerations with a rule that an injunction automatically follows a determination that a patent has been infringed. *Id.* at 392-93 (discussing Supreme Court’s refusal to automatically grant injunction upon a finding of copyright infringement). Thus, a court faced with a request for an injunction in a patent infringement case must apply the traditional four-factor test and may not apply a general rule that a permanent injunction will issue once infringement and validity have been demonstrated. *Id.* at 393-94.

To be sure, *eBay* dealt with the issuance of a permanent injunction, not a preliminary injunction. Furthermore, the Supreme Court rejected a categorical rule that a patent holder is entitled to an injunction upon a showing of infringement. It did not explicitly address the propriety of applying a presumption of irreparable harm upon a showing of a likelihood of success on the issue of infringement.

In the wake of the *eBay* decision, the Federal Circuit has yet to issue a published opinion that directly rejects the presumption of irreparable harm in a lawsuit seeking a preliminary injunction for patent infringement. *See Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 n.9 (Fed. Cir. 2006) (declining to address applicability of presumption after *eBay* because plaintiff established irreparable harm). In an unpublished opinion, however, the Federal Circuit, faced with a preliminary injunction motion in a patent infringement case, concluded that after *eBay*, “the presumption of irreparable harm, based just on proof of infringement, was discarded. The burden is now on the patentee to demonstrate that its potential losses cannot be compensated by monetary damages.” *Automated Merch. Sys., Inc. v. Crane Co.*, 357 F. App’x 297, 301 (Fed. Cir. 2009). This holding, which relied

on *eBay*, is consistent with the Federal Circuit’s pronouncement that the “standard for a preliminary injunction is essentially the same as for a permanent injunction with the exception that the plaintiff must show a likelihood of success on the merits rather than actual success.” *Abbott Labs.*, 544 F.3d at 1364 (quoting *Amoco Prod. Co. v. Vill. of Gambell, AK*, 480 U.S. 531, 546 n.2 (1987)).

The procedural posture of the *eBay* case did not dictate its outcome. Additionally, if a presumption of irreparable harm does not arise upon a showing of success on the merits, it is difficult to see why it should arise upon the lesser showing of likelihood of success on the merits. Furthermore, a preliminary injunction is an “extraordinary and drastic remedy.” *Munaf v. Geren*, 553 U.S. 674, 689 (2008). Allowing a plaintiff to obtain a preliminary injunction upon a showing of only three of the four factors of the traditional test for granting such injunctions would provide an unfair advantage to those seeking such drastic relief. Furthermore, while the Federal Circuit has not explicitly ruled on this issue, following *eBay*, “it appears that the presumption of irreparable harm is at best on life support.” *Red Bend Ltd. v. Google Inc.*, Civ. A. No. 09-11813, 2011 WL 1288503, at *18 (D. Mass. Mar. 31, 2011). It is time to pull the plug.

Since the *eBay* decision, a number of district courts have held that a presumption of irreparable harm is no longer appropriate upon a finding of infringement. *See, e.g., FieldTurf USA, Inc. v. Astroturf, LLC*, 725 F. Supp. 2d 609, 617 (E.D. Mich. 2010); *Mike’s Train House, Inc. v. Broadway Ltd Imports*, 708 F. Supp. 2d 527, 532 n.5 (D. Md. 2010); *Acoustic Processing Tech., Inc. v. KDH Elec. Sys., Inc.*, 697 F. Supp. 2d 146, 156-57 (D. Me. 2010) (“Thus, to obtain injunctive relief, a party can neither rely upon a presumption of irreparable nor point to merely possible harm. Instead, whether a patent case or not, it must show that irreparable harm is likely.”); *Bushnell, Inc. v. Brunton Co.*, 673 F. Supp. 2d 1241, 1260-62 (D. Kan. 2009) (collecting cases); *Voile Mfg. Corp.*

v. Dandurand, 551 F. Supp. 2d 1301, 1306 (D. Utah 2008); *Tiber Labs., LLC v. Hawthorn Pharms., Inc.*, 527 F. Supp. 2d 1373, 1380 (N.D. Ga. 2007); *Sun Optics, Inc. v. FGX Int'l, Inc.*, Civ. A. No. 07-137, 2007 WL 2228569, at *1 (D. Del. Aug. 2, 2007); *Torspo Hockey Int'l, Inc. v. Kor Hockey Ltd.*, 491 F. Supp. 2d 871, 881 (D. Minn. 2007); *but see Powell v. Home Depot U.S.A., Inc.*, Civ. A. No. 07-80435, 2009 WL 3855174, at *13 (S.D. Fla. Nov. 17, 2009) (“[T]his Court concludes that the presumption of irreparable harm in the context of preliminary injunctions should survive *eBay*.”); *Eisai Co. v. Teva Pharms. USA, Inc.*, Civ. A. Nos. 05-5727 & 07-5489, 2008 WL 1722098, at *10 (D.N.J. Mar. 28, 2008); *Christiana Indus. v. Empire Elecs., Inc.*, 443 F. Supp. 2d 870, 884 (E.D. Mich. 2006).

The *Powell* court offered two reasons that the presumption of irreparable harm survived *eBay*. First, the court did not consider the presumption of irreparable harm inconsistent with the holding in *eBay*; the Supreme Court rejected a categorical approach in granting or denying injunctive relief without considering the equities. 2009 WL 3855174, at *13 (citing *eBay*, 547 U.S. at 393-94). A presumption did not run afoul of the Supreme Court’s directive because it merely shifted the burden to the infringer. Furthermore, courts still were required to determine if the balance of hardships tilted in the patentee’s favor and if the public interest favored granting injunctive relief. Thus, the presumption did not categorically establish injunctive relief upon a showing of likelihood of success on the merits. *Id.* Second, the court in *Powell* reasoned that the Supreme Court was aware of the unique nature of patent cases and the difficulty of protecting a right to exclude solely through monetary damages. Thus, *eBay* merely requires that the four-factor injunction standard be applied to patent cases. *Id.*

Neither of these reasons persuades this Court that the presumption of irreparable harm

survive *eBay*. First, although no factor is dispositive, the party seeking relief must demonstrate *both* a likelihood of success on the merits and irreparable harm. *Amazon.com*, 239 F.3d at 1350. If the patentee fails on either prong, it is not entitled to an injunction. The practical effect of a presumption of irreparable harm upon a showing of a likelihood of success on the merits cannot be ignored: it places a burden upon the purported infringer to prove the absence of irreparable harm and in essence allows the patentee to meet two prongs of the four-factor test if it can carry its burden on one prong; the presumption collapses a four-part test into a three-part test, which runs contrary to the holding in *eBay*. Second, the Court finds it difficult to imagine a situation in which a patentee can show a likelihood of success on the merits and receives the presumption of irreparable harm, yet is denied injunctive relief because the balance of hardships and public interest favor denial of its motion. Finally, the *eBay* Court was not faced with a situation in which the Federal Circuit categorically awarded injunctive relief upon a showing of infringement and validity. Instead, the Federal Circuit applied its rule that injunctive relief should issue “absent exceptional circumstances.” While the Supreme Court rejected a categorical approach, it did so in the context of a rule that presumed injunctive relief. The *Powell* court thus read *eBay* too narrowly.

Furthermore, a presumption of irreparable harm is inequitable. Rather than balance all of the factors on equal scales after the parties have submitted their evidence, courts must perform such balancing with a finger already placed on the scale of the patentee upon a showing of likelihood of success on the merits. It would allow a court to find that a patentee sustained its burden of showing irreparable harm without any additional evidence if the patentee could show a likelihood of success on the merits and the alleged infringer could not present evidence negating a showing of irreparable harm. Such an outcome is inconsistent with *eBay* and the traditional four-factor test applied for

injunctive relief.

This Court therefore joins those that have concluded that the presumption of irreparable harm no longer applies, and concludes that the previously accepted two-for-the-price-of-one presumption of irreparable harm is no longer the law. Precision Medical must demonstrate that its potential losses cannot be compensated by monetary damages. *See Automated Merch.*, 357 F. App'x at 301.

2. *Precision Medical's evidence of irreparable harm*

Precision Medical does not rely solely on the presumption of irreparable harm. Rather, it claims that it can demonstrate such harm and that it will continue to suffer such harm unless Defendants' alleged infringement is enjoined.

First, Defendants have undercut Plaintiff's prices. While Precision Medical sold its vacuum regulator for between \$295 and \$325 per unit, Defendants have offered their products for as low as \$175 per unit. (Shuman Decl. ¶ 10.) Precision Medical claims that Defendants can offer such a reduced price because they are free-riding off of its research and development efforts and are likely using inferior materials and making their products overseas. (*Id.* ¶ 19.) This pricing scheme has forced Precision Medical to lower its price to \$200 per unit. (*Id.* ¶ 10.) This price decrease will cause Plaintiff to lose market share and renders it impossible for Precision Medical to effectively compete. (*Id.* ¶¶ 11, 19.) Because of Defendants' "vastly lower prices, this steep price decline will continue until Precision Medical is forced out of this product market." (Shuman Decl. ¶ 10.) The nature of the market is such that once lower prices prevail, the markets will no longer accept higher prices, which will cause "a permanent and immeasurable loss of revenue and market share to Precision Medical even after the infringement is stopped." (*Id.*)

Furthermore, Shuman stated that Precision Medical has lost market share in the past involving similar products and under similar circumstances; once market share is lost it cannot be regained. (*Id.* ¶¶ 11-12, 19-20.) Specifically, Shuman recounted Precision Medical’s bad experience with oxygen regulators once “knock-off imports” entered the market. (Hr’g Tr. I at 167-68.) These imports forced Precision Medical to lower its prices to avoid losing market share. (*Id.* at 168.) Eventually, Precision Medical “got destroyed on this market by imports” and it was unable to recapture lost market share. (*Id.*) Precision Medical also suffered a similar loss of market share in the nebulizer market, and eventually left that market. (*Id.* at 169-71.)

Precision Medical also points to the unique sales and distribution structure of the medical device market to sustain its claim of irreparable harm. (Pl.’s Mem. at 21-22; Pl.’s Post-Hr’g Br. at 12-13.) The ultimate purchaser of a vacuum regulator buys its product through a group of distributors and independent sales representatives across the country. Thus, it is not Precision Medical, the device manufacturer, that has a direct relationship with the end customer. (Shuman Decl. ¶¶ 15-16.) Precision Medical has cultivated relationships with salespeople and distributors over a long period of time, and they are central to Precision Medical’s existence. (*Id.* ¶ 15.) Each sales representative and distributor maintains an exclusive relationship with Precision Medical and does not sell competing products. (*Id.*) Defendants have been soliciting sales representatives with promises of increased sales and lower-cost products(*Id.* ¶ 16.) If Defendants are successful, Precision Medical risks losing its distribution channels, which would damage its business, revenue, and reputation. (*Id.*; Pl.’s Mem. at 22.)

Precision Medical also notes that Defendants’ products are more likely to fail “because the materials they use are inferior” and when they do, customers will switch to alternative designs,

further eroding Plaintiff's market share. (Shuman Decl. ¶ 17; Pl.'s Mem. at 22-23.) Finally, if Plaintiff loses sales in the intermittent vacuum regulator market, it will likely lose sales of its continuous-only regulators, which are often purchased with intermittent vacuum regulators. (Shuman Decl. ¶ 7.)

During the preliminary injunction hearing, Shuman expanded on the intermittent vacuum regulator market. The market is comprised of three national distributors and a number of independent dealers. (Hr'g Tr. I at 172.) Precision Medical has about thirty independent dealers totaling approximately eighty salespeople. (*Id.*) Precision Medical's national distributor for the past twenty-years is Tri-anim. (*Id.* at 194.) Genstar uses Medline. (*Id.*) Precision Medical has 25% or 30% of the vacuum regulator market. (*Id.* at 202.) Ohio Medical is the market leader. (*Id.* at 203, 216.) At the hearing, Shuman expressed concern that Tenacore or Genstar would approach Tri-anim and independent dealers in an effort to poach their business. (*Id.* at 173.) Over time, if Defendants were able to convince independent dealers to begin selling their products, eventually the national salespeople would also switch. (*Id.* at 173-74.) Precision Medical could lose half of its business in a matter of months. (*Id.* at 174.)

Shuman stated that Precision Medical's average price to the dealer is \$225 to \$300. (*Id.* at 174.) Genstar or Tenacore have reportedly offered its product to the dealer for \$175. (*Id.*) Because the dealer and hospital directly negotiate prices, the lower the cost of a unit, the more profit the dealer or distributor will realize. (*Id.* at 175.) Shuman expressed concern that if Defendants are permitted to sell their products at such a low price, the price will spiral down and Precision Medical will lose significant market share, which they will never recover. (*Id.* at 179.)

Precision Medical's sales of intermittent vacuum regulators decreased from 2005 to 2006,

although they increased in 2007 and 2008. (*Id.* at 213.) They decreased from 2008 to 2009. (*Id.* at 214.) Sales were flat from 2009 to 2010. (*Id.* at 215.)

Suzanne Moyer is the director of hospital sales and national sales manager for Precision Medical. (Hr'g Tr. I at 237.) Although she is the person at Precision Medical most familiar with competitors, she testified that she did not investigate competitors' booths while attending trade shows where Precision Medical and its competitors appeared. (*Id.* at 237-38.) She confirmed that Precision Medical sells its products through a national distributor, numerous independent dealers, and commissioned sales representatives who work with the distributors. (*Id.* at 239.) Precision Medical has very little contact with the end users of its products. (*Id.* at 237, 239.)

Moyer stated that sales representatives asked Precision Medical to equal or beat lower prices from Genstar or Tenacore. (*Id.* at 241.) Because Precision Medical does not use exclusive contracts to distribute its products, a sales dealer would be very interested in getting a product at a lower price and selling it at the current price, thereby increasing its profits. (*Id.* at 242-43.) Precision Medical can only lower the price of its product so much before it must exit the market. (*Id.* at 244.) Plaintiff also produced e-mails discussing the low prices Genstar and Tenacore offered. (Pl.'s Prelim. Inj. Hr'g Exs. 25-27, 30 [Moyer e-mails].)

Tenacore counters that its market share is minuscule and thus unlikely to damage Precision Medical. (Tenacore's Opp'n at 22.) Additionally, its sales can be recorded and money damages can thus be calculated if Tenacore is ultimately found to have infringed the '308 Patent. Both Defendants also contend that courts have held that allegations of lost sales and pricing and market erosion are insufficient to demonstrate irreparable harm. (*Id.* at 22-23; Genstar's Opp'n at 6.)

Lost sales alone are insufficient to show irreparable harm because they can be compensated

through money damages. *Automated Merch.*, 357 F. App'x at 300-01 (“[N]o matter how much evidence of lost revenue [the plaintiff] presented, this evidence by itself could not support a finding of irreparable harm.”); *see also Abbott Labs. v. Andrx Pharms., Inc.*, 452 F.3d 1331, 1348 (Fed. Cir. 2006) (“[I]f this court were to accept a patentee’s argu[ments] that, apart from the presumption, its potential lost sales alone demonstrate manifest irreparable harm, acceptance of that position would require a finding of irreparable harm to every manufacturer/patentee, regardless of circumstances.”) (internal quotation marks omitted). A plaintiff must at least present evidence of lost market share in the absence of a preliminary injunction. *See Automated Merch.*, 357 F. App'x at 300-01. Speculative claims of potential lost market share will not sustain a finding of irreparable harm because a “possible market share loss would apply in every patent case where the patentee practices the invention.” *Nutrition 21 v. United States*, 930 F.2d 867, 871 (Fed. Cir. 1991). A party can show irreparable harm however if it presents evidence that the failure to grant a preliminary injunction would allow an infringer to drop its prices in order to drive the patent holder out of the market entirely. *Automated Merch.*, 357 F. App'x at 301.

Precision Medical’s claims for irreparable harm are speculative. The fact that Shuman considers this situation similar to another in which “low-cost products” flooded the market is not evidence that it has lost revenue or market share here, particularly as Precision Medical’s prior experience involved different products. The evidence Precision Medical submitted shows that its sales of intermittent vacuum regulators has remained fairly stable since Defendants entered the market, and that Plaintiff is not at risk of losing its distributors or market share. All that Precision Medical has put before this Court is a statement that in a direct bidding situation, it was forced to lower its price. This is simply competition and cannot serve as the basis for granting a preliminary

injunction. Given Plaintiff's current market position and sales figures, any harm suffered by Precision Medical can be remedied by money damages.

Although Precision Medical asserts a parade of horrors that might befall it should it lose its national distributor, it presented no evidence that it was in danger of losing its relationship with Tri-anim. Furthermore, because each national distributor sells only one product line, a preliminary injunction against Defendants would ensure that they would lose their national distributors. Finally, the evidence shows only a slight decrease in sales from 2009 to 2010 and Precision Medical forecasts sales in 2011 to be similar to those from 2010. Thus, this Court is left with evidence that Defendants have tried to sell their products at lower prices. Absent evidence of unfair competition, this Court cannot enjoin smaller companies from competing against a larger one in an effort to gain a larger market share. Precision Medical's representatives expressed their belief that they were putting out a better product and that Defendants were pushing poorly constructed devices whose defects in quality and craftsmanship left them less desirable and reliable. It is therefore difficult to see how Defendants can capture market share from Precision Medical or how hospitals and nursing homes will continue to pay for inferior products that will leave patients vulnerable to needless suffering.

3. Delay in seeking a preliminary injunction

Genstar argues that Precision Medical is not entitled to a preliminary injunction because it waited over three years to seek such relief and therefore it cannot show irreparable harm. (Genstar's Opp'n at 4-5.)

Delay in seeking a preliminary injunction is an important factor to consider when addressing the need for injunctive relief. *High Tech Med. Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F.3d 1551, 1557 (Fed. Cir. 1995). The Federal Circuit has not set forth a specific time limit after

which delay in bringing a preliminary injunction motion disproves an irreparable harm argument. Courts have been all over the map on the issue. *Compare T.J. Smith and Nephew Ltd. v. Consol. Med. Equip.*, 821 F.2d 646, 648 (Fed. Cir. 1987) (fifteen-month delay negated irreparable harm); *and Capital Machine Co. v. Miller Veneers, Inc.*, Civ. A. No. 09-702, 2010 WL 3000769, at *1 (S.D. Ind. July 28, 2010) (waiting over a year from start of litigation before filing motion for preliminary injunction deemed too long); *and Quad/Tech, Inc.*, 701 F. Supp. 2d at 657 (holding that fourteen-month delay between discovery of alleged infringement and filing for injunctive relief “undercuts the urgency that forms the cornerstone of injunctive relief; indeed, this delay indicates a lack of urgency”) *with High Tech Med.*, 49 F.3d at 1557 (concluding that seventeen-month delay, “standing alone,” is insufficient to demonstrate absence of irreparable harm though it did militate against awarding injunctive relief); *and Young v. Lumenis, Inc.*, 301 F. Supp. 2d 765, 772 (S.D. Ohio 2004) (filing lawsuit after reasonable time to investigate possible infringement and waiting less than two months after filing lawsuit to file motion for preliminary injunction held not excessive); *Panduit Corp. v. Band-It-Idex, Inc.*, Civ. A. No. 00-1461, 2000 WL 1121554, at *24 (N.D. Ill. June 27, 2000) (concluding that nine-month delay between discovery of alleged infringement and lawsuit “is a factor that raises questions concerning Panduit’s claim of irreparable harm, but does not destroy it”).

Here, Precision Medical filed its patent infringement lawsuit on October 1, 2010 and filed its motion for preliminary injunction on January 14, 2011, a span of over three months. Although this is not a significant period of time, Genstar claims that Precision Medical knew of sales of Genstar’s allegedly infringing product as early as 2007, or at least no later than mid-2008. This would constitute a delay of two to three years. Precision Medical denies having knowledge of Genstar’s sales, claiming that it only learned of its infringing device shortly before filing this lawsuit.

(Shuman Supplemental Decl. ¶ 4.) Precision Medical's representatives, Shuman and Moyer, testified that they did not learn of the accused products until the summer of 2010. (Hr'g Tr. I at 176-77, 248.) Finally, Precision Medical did not hesitate in seeking a preliminary injunction once it became apparent that Defendants insisted on selling their infringing products. (Pl.'s Reply at 13.)

Genstar submitted evidence that its representatives attended multiple industry trade shows that representatives of Precision Medical also attended. (Genstar Prelim. Inj. Hr'g Exs. 18, 20-23 [Trade Show Publications].) Genstar also published a flyer around 2007 showing vacuum regulators, including its continuous/intermittent regulators. (Genstar Prelim. Inj. Hr'g Ex. 19 [Flyer].) Genstar also advertised its continuous/intermittent vacuum regulators in the May/June 2007, March 2008, and December 2008 issues of *Respiratory Management*. (Genstar Prelim. Inj. Hr'g Exs. 24-26 [Genstar Ads].)

Although Genstar contends that Precision Medical advertised in this publication, the Court finds no evidence that both companies advertised in this publication at the same time. Rather, the magazine included Precision Medical in its editorial product section. Furthermore, Genstar was unable to elicit any evidence from Moyer that she placed any advertisements for Precision Medical or even saw any of Genstar's advertisements in *Respiratory Management*. She further testified that while she may have attended trade shows on behalf of her employer, she did not seek out information about Precision Medical's competitors or learn about their products. (Hr'g Tr. I at 238.) Although this lack of knowledge about a competitor's activities in the market might not be the best business practice, Moyer's testimony in this respect was unchallenged and the Court considers her credible on the topic. Furthermore, Genstar's advertisements in all three issues of *Respiratory Management* are virtually identical; both the May/June 2007 issue and the December 2008 issue claim that the

continuous/intermittent suction regulator by Genstar is a new product. Thus, one seeing only this last issue might believe that the Genstar product just arrived on the market in late 2008. Of course, that would still evince a delay of over two years, but it highlights the flaw in Genstar's argument: it is unclear when Precision Medical first learned of Defendants' accused products. Finally, the e-mails submitted by Precision Medical are consistent with Moyer's testimony that she first learned of Genstar and Tenacore around March of 2010; this motion followed within a year. (*See* Moyer emails.) While increased vigilance on the part of Precision Medical could have brought this issue to light earlier, the Court cannot deem Precision Medical's delay unreasonable. Accordingly, the record before the Court does not support a finding that Precision Medical's delay in seeking a preliminary injunction against Genstar precludes a finding of irreparable harm.

Genstar also claims that Precision Medical has ignored a larger competitor in the market even though its product has a substantially similar timing device as those accused of infringement. (Genstar's Opp'n at 5.) Apparently, this is indicative of Plaintiff's selective enforcement of its patent. Not so, insists Plaintiff. First, there is no requirement that Precision Medical sue all alleged infringers at the same time. Second, Plaintiff made a business decision not to sue because no competitor has undersold Precision Medical to the extent Defendants have, and because no competitor previously targeted Plaintiff's distributor. (Pl.'s Reply at 13-14.)

The parties in this case are not the only players in the intermittent vacuum regulator market. For example, Allied Healthcare sells a product that Krupa claimed was identical to the product that Precision Medical sells. (Hr'g Tr. I at 142-43.) Shuman testified that it has not sued Allied Healthcare because it is a fading company with poor distribution and quality problems, and is thus not a threat to Precision Medical. (Hr'g Tr. I at 161.) Additionally, their pricing is similar to that

of Precision Medical. (*Id.*)

Plaintiff correctly notes that it is not obligated to simultaneously sue every infringer. *See Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 429 F.3d 1364, 1381 (Fed. Cir. 2005). But the failure to file a lawsuit against other potential infringers is relevant to an irreparable harm analysis when it shows unreasonable delay, a willingness to accept royalty damages in lieu of market exclusivity, or indifference in enforcing one's patent. *See Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 976 (Fed. Cir. 1996). This is not a situation, however, in which Precision Medical is engaging in a step-by-step plan to sue purported infringers. Rather, it is suing a small player and a virtually non-existent player in an effort to foreclose them from the market. Meanwhile, a larger competitor remains free to violate its patent.

The Court concludes that these actions weaken Precision Medical's irreparable harm argument because its decision to sue only these two Defendants undercuts its contention that it fears losing market share. It also demonstrates a selective enforcement of its patent that can be compensated by money damages. Precision Medical contends that Allied Healthcare has not drastically reduced prices nor has it had any effect on Precision Medical's market share. But Precision Medical provided no evidence that it has lost market share to Defendants, and the sales data it presented offered no evidence of lost sales or a decrease in prices. Furthermore, Precision Medical's projections for 2011 indicate that its sales will be similar to its 2010 figures. Finally, it appears as though the market also contains several non-infringers, which also lessens the possibility of irreparable harm. *See Serio-US Indus. v. Plastic Recovery Techs. Corp.*, 267 F. Supp. 2d 466, 469 (D. Md. 2003). The Court concludes that Plaintiff's claim of irreparable harm is further diminished by its conduct and that ultimately, Plaintiff cannot make a showing of irreparable harm.

IV. CONCLUSION

Plaintiff has failed to demonstrate a likelihood of success on the merits or to show irreparable harm if a preliminary injunction is not granted. A failure to carry its burden on either of these issues is grounds for denial of the request for a preliminary injunction. Accordingly, this Court need not consider the balance of the harm or the public interest. Precision Medical's motion for a preliminary injunction is denied. An Order consistent with this Memorandum will be docketed separately.